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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,735	08/04/2000	Maria Isabel Baeza-Ramirez	RG0107US (#90236)	2762

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/13/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/632,735

Applicant(s)

BAEZA-RAMIREZ, MARIA ISABEL

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-90 is/are pending in the application.
- 4a) Of the above claim(s) 39-45 and 60-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-38 and 46-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-90 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 32-38 and 46-59, in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 32-38 and 46-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposomes and neoplastic cells, does not reasonably provide enablement for all lipidic particles, as recited in claims 32 and 46. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses liposomes and neoplastic cells as antigens containing lipidic particles for use with the present invention, and does not mention the use of other antigens. Due to the lack of working examples and proper guidance to use other antigens with lipidic particles with the present invention, undue burden would be placed on one of skill in the art to practice the invention, as claimed.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 32-38 and 46-59 are rejected under 35 U.S.C. 102(a) as being anticipated by Aguilar et al. (J. Biol. Chem., 1999). Aguilar et al. disclose liposomes prepared from hexagonal phase-preferring lipids, such as phosphatidate, cardiolipin, and phosphatidylserine, in TBS buffer (pH 7.0). Polyclonal antibodies were developed using Mn ion induced liposomes as the antigen. Monoclonal antibodies were produced, and reaction of these antibodies with the lipid particles was observed by ELSIA and flow cytometry. Liposomal ELISA was carried out by coating ELISA wells with liposomes. The wells were incubated with monoclonal antibodies. Peroxidase-conjugated goat anti-mouse polyvalent or anti-mouse IgM antibodies were then used. This allowed detection of bound antibodies. For flow cytometry, a negative control of irrelevant monoclonal antibody of IgM isotype was used. The results of the paper are the first evidence that nonbilayer lipid structures are present in cells and may be involved in production of antiphospholipid autoantibodies, which participate in the development in antiphospholipid syndrome.

6. Claims 32-38, 46-48, 54-56, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramirez et al. (Instituto Politecnico Nacional, 1994 or 1997). Both references disclose unilamellar liposomes formed from phosphatidylcholine:phosphatidate bearing lipidic particles induced by Mn ions. Polyclonal antibodies with reactivity toward these lipidic particles were produced. Monoclonal antibodies of IgM isotype reacted with the lipidic particles, which was detected by cytofluorometry and ELISA. It is inherent that the antibody-lipid particle complex was labeled for detection. The references also disclose that the determination of

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antibodies to lipid particles in the sera from patients of antiphospholipid syndrome and systemic lupus indicates that the lipid particles induce production of the antibodies.

7. Claims 32-38, 46-48, 54-56, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramirez et al. (Instituto Politecnico Nacional, 1998). The reference discloses the characterization of antibodies that recognize lipidic particles that were induced by chlorpromazine or procainamide. An antiphospholipid antibody syndrome was developed. Liposomes carrying lipidic particles were characterized by flow cytometry or NMR. Polyclonal antibodies that showed reactivity to the lipid particles induced by Mn ions were produced, and the reaction was observed by flow cytometry. The antibodies were of IgM and/or IgG isotype. The experiments suggest that formation of antiphospholipid antibodies is the first event that develops in antiphospholipid antibody syndrome, probably due to cellular damage.

#### ***Response to Arguments***

8. Applicant's arguments with respect to the art rejections over claims 32-38 and 46-59 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments with respect to the rejection under 35 USC 112, first paragraph (scope) are not persuasive. Although applicant has amended the claims to exclude serum detection, applicant still has only enabled the use of liposomes and neoplastic cells as the antigen for use with the invention, and not all lipidic particles.

#### ***Conclusion***

Claims 32-38 and 46-59 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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February 11, 2002